

**SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING**

DECEMBER 4, 2015

The Committee met by teleconference on Friday, December 4, 2015, at 11:00 am EST. Chair Shawn Kassner led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (Other)	Absent
Kareen Baker, Independent (Other)	Absent
Nicole Cairns, NYSDOH (Other)	Present
Rachel Ellis, NJ DEP (AB)	Present
Patrick Garrity, KYDOW (AB)	Present
Scott Hoatson, Oregon DEQ (AB)	Present
Craig Huff, ERA (Other)	Absent
Shawn Kassner, Phenova (Chair; Other)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Absent
Mitzi Miller, Dade Moeller Assocs. (Other)	Present
Tim Miller, Phenova (Other)	Present
Judy Morgan, Pace (Lab)	Present
Joe Pardue, P2S (Vice-Chair; Other)	Present
Donna Ruokonen, Microbac (Lab)	Present
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Present
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Steve Arpie, Absolute Standards; Mike Blades, ERA; Amanda Bruggeman, Phenova; Audrey Cornell, ERA; Brian Stringer, ERA.

2 – Previous Minutes

It was moved by Mitzi and seconded by Judy to approve the minutes of November 20, 2015. All were in favor.

3 – Sub-Committee Update

Shawn reported he was waiting for notification from the homogeneity/verification subcommittee that was looking into the analytical method requirements for PT Providers.

4 – Comments on V3 and V4 Voting Draft Standards

Those comments considered previously, but that were still outstanding were addressed.

Regarding Joe's assigned comment on **5.4.3.1(a), 5.4.3.2, 5.4.3.3, 5.4.3.4**, Shawn had re-worded a section. The commenter had correctly stated that laboratory requirements cannot be in V3, and had recommended adding as a laboratory requirement in V1M1 that the laboratory shall notify the PTP that the PT sample will be used for corrective action purposes so the PTP may ensure that the PT sample supplied meets the requirements for supplemental PT. However, Shawn rightly pointed out

this could not be added to that module at the Interim Standard stage, since the section had passed at the Voting Draft Standard stage. On Mitzi's suggestion it was added as a "parking lot" item for the next revision of the standard. She suggested, in the meantime, wording the V3 section to require the provider to ask the laboratory if it is a supplemental PT. The PT Providers on the call said they already ask that question of the laboratories, and there was reluctance to make this a requirement in the standard. On Scott's suggestion, the items in the 5.4.3 section were re-ordered. It was suggested to add a note that it is in the best interest of the laboratory and the PT Provider that this information is gathered at the time the supplemental PT is requested. Shawn said he would do the reorganization and add the note for discussion and vote at the next meeting. This would also address the other similar comments on those sections.

The only outstanding issue from Judy's assigned comments pertained to **5.6.1.4**, where a commenter had asked "*What are "ISO Guide 34 materials"?*" Shawn provided the definition of "ISO Guide 34 Reference Material" taken from ISO Guide 34: (2009)E.

"ISO Guide 34 Reference Material – a material manufactured by the PT provider shown to be, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (per ISO Guide 34:(2009)E)."

It was moved by Scott and seconded by Judy to put this as **3.22** in the definition section. All were in favor.

Nicole added that **5.6.1.4** should be amended to state "the analysis of" before "calibration standards". Shawn said he would make that editorial change.

A comment assigned to Nicole on **5.4.4** was being held until the PTPEC had provided feedback. Nicole suggested that re-wording 5.4.3 would allow 5.4.4 to be deleted. This was so moved by Mitzi and seconded by Joe. All were in favor.

All of Shawn's assigned comments on V4 were discussed.

A general comment of redundancies with ISO 17011 mirrored more specific comments that are described below. It was moved by Nicole and seconded by Scott to find the comment Non-Persuasive. All were in favor.

6.3.1(c) "*The AB does not approve changes, the AB reviews that have been done in conformance to the relevant standard requirements. ANAB does this during assessments, both reaccreditation assessments and surveillance assessments. Possible Resolution: Remove this redundant to ISO/IEC 17011 3.7.*" Shawn suggested this was Non-Persuasive, stating the PTPA is assessing the appropriateness of the documentation and the validity of the change to the initial assigned value to the TNI V3 standard, just as it applies to assessing the appropriateness of homogeneity and stability testing as TNI specific requirements. However, he considered it Persuasive to clarify the requirement, and suggested editing it to "verification of the appropriate documentation and technical reasoning applied to adjustments to initial assigned values." It was so moved by Judy and seconded by Mitzi. All were in favor.

6.3.5 *“Redundant to ISO/IEC 17011 and AB requirements documents. ISO/IEC 17011 8.1.2, “The accreditation body shall require that it is informed by the accredited CAB, without delay, of significant changes relevant to its accreditation, in any aspect of its status or operation relating to*
a) its legal, commercial, ownership or organizational status,
b) the organization, top management and key personnel,
c) main policies,
d) resources and premises,
e) scope of accreditation, and
f) other such matters that may affect the ability of the CAB to fulfill requirements for accreditation.””

It was moved by Scott and seconded by Donna that the comment was persuasive and 6.3.5 would be deleted as redundant to ISO 17011 Section 8.1.2. All were in favor.

6.3.6 *“Redundant to ISO/IEC 17011 and AB requirements documents. ISO/IEC 17011 7.11.7 The accreditation body may conduct extraordinary assessments as a result of complaints or changes (see 8.1.2), etc. The accreditation body shall advise CABs of this possibility. Possible Resolution: Remove Clause.”* Nicole pointed out that 6.3.6 includes the requirement that the visits are fully documented, but 17011 does not include that requirement. On discussion it was agreed that requirement must remain. It was moved by Mitzi and seconded by Judy to rule the comment Persuasive and to re-word the clause to read “The causes and resolution of extraordinary on-site assessments of the PT Providers shall be fully documented.” All were in favor.

5 – Next Meeting

Mitzi and Rachel’s V4 comments would be discussed. The comments on V3 would be completed with the PTPEC and the subcommittee’s input. The goal was to have the Interim Standards for V3 and V4 posted in January. Also for the next meeting, Shawn would circulate the comments received on the V1M1 and V2M2 Interim Standards. Everything should then be completed by March 2016.

Adjournment

The meeting was adjourned at 12:15 pm EST.